

**Appendix 4: Serious adverse events reported in observational studies of medical cannabinoid preparations**

Serious adverse event*	No. (%) of events
Nervous system disorders	9 (23)
Convulsion	3
Relapse of multiple sclerosis	2
Myoclonus	2
Balance disorder	1
Circulatory collapse	1
Psychiatric disorders: mental disorder	4 (10)
Respiratory, thoracic and mediastinal disorders	4 (10)
Pneumonia	2
Lung neoplasm malignant	1
Pleurisy	1
Gastrointestinal disorders	3 (8)
Diarrhea	2
Vomiting	1
Musculoskeletal and connective tissue disorders	3 (8)
Muscle spasm	1
Muscular weakness	1
Osteomyelitis	1
Renal and urinary disorders: urinary tract infection	3 (8)
Vascular disorders	3 (8)
Deep vein thrombosis	1
Orthostatic hypotension	1
Syncope vasovagal	1
Neoplasm benign, malignant and unspecified: breast cancer	2 (5)
Skin and subcutaneous tissue disorders	2 (5)
Cellulitis	1
Decubitus ulcer	1
Blood and lymphatic system disorders: lymphadenopathy	1 (3)
Cardiac disorders: ventricular extrasystoles	1 (3)
Hepatobiliary disorders: biliary cirrhosis	1 (3)
Infections and infestations: sepsis	1 (3)
Investigations: abnormal result on liver function test	1 (3)
Metabolism and nutrition disorders: dehydration	1 (3)
Total	39 (100)

\*Grouped by system order classes of the *Medical Dictionary for Regulatory Activities*.<sup>1</sup>

**Reference**

1. *Medical dictionary for regulatory activities*. Version 10.0. Los Angeles: Northrop Grumman Corporation; 2008. Available (by subscription): [www.meddrmsso.com/](http://www.meddrmsso.com/) (accessed 2008 Mar 25).